

## **REMARKS**

### **Interview Request**

Applicants thank the Examiner for acknowledging their request for a telephonic interview (see page 4, of the OA), and Applicants' representative will follow up with the Examiner soon after submission of this response and amendment.

### **Status of the Claims**

Upon entry of this amendment, claims 1-3, 5-15, 17-23, 27-30, 33-35, 38, 40-43, 45, 47, 48, 50, 52, 53, 56-59, 61-64, 66-71, 83-88, 90, 93, 94 and 97-101 are pending, claims 4, 16, 24-26, 31, 32, 36, 37, 39, 44, 46, 49, 51, 54, 55, 60, 65, 72-82, 89, 91, 92, 95 and 96 are cancelled without prejudice or disclaimer, and claims 1, 45, 47, 90, 100 and 101 are amended.

### **Amendments to Claims**

Claim 1 has been amended to correct a grammatical error.

Claims 45 and 90 have been amended to clarify one aspect of the claimed invention. Support for this amendment can be found, *inter alia*, in paragraphs [0050] and [0051] of U.S. patent application publication no. 20040062756 (the publication of this application).

Claim 47 has been amended to clarify one aspect of the claimed invention. Support for this amendment can be found, *inter alia*, in paragraphs [0025], [0026], [0065], [0099], [0105], and [0106] of U.S. patent application publication no. 20040062756.

Claims 100 and 101 have been amended to clarify one aspect of the claimed invention.

### **Restriction Requirement**

The Examiner has required restriction under 35 U.S.C. § 121 between the following four groups:

- I. claims 1-15, 17-24, 27-30, 33-45, 47-48, 50, 52-53, 56-59, 61-64, 66-71, 83-84, 88-90, 93-94 and 97-101 drawn to *in vitro* *ex vivo* methods of transducing primary lymphoid cells,

myeloid cells, or hematopoietic progenitor cells using a lentiviral vector and cell surface binding molecule, classified in class 435, subclass 456;

II. claim 85, drawn to a method for the introduction of transduced cells into a living subject, classified in class 435, subclass 325;

III. claim 86, drawn to a method for the introduction of transduced cells into a tissue or organ, classified in class 435, subclass 325; and

IV. claim 87, drawn to a method for the introduction of transduced cells into a blastocyst, classified in class 435, subclass 325.

The restriction was required because each of the identified groups is allegedly directed toward a different method that accomplishes different scientific objectives and employs disparate methodology steps and scientific reagents.

Applicant hereby provisionally elects, without traverse, **Group I** (claims 1-15, 17-24, 27-30, 33-45, 47, 48, 50, 52-53, 56-59, 61-64, 66-71, 83-84, 88-90, 93-94 and 97-101) for continued examination. Of elected Group I, claims 4, 24, 36, 37, 39, 44, and 89 have been canceled.

However, Applicants respectfully traverse the restriction requirement between groups II, III and IV because the methods of claims 85-87 are classified in the same class (435) and subclass (325) and therefore would not require separate searches. Thus, it would not be an undue burden on the Patent Office to examine these three claims together.

### **Species Election**

The Examiner further required that if Applicants elect Group I, they must also identify and elect a single cell target, the genotype/phenotype of the desired cell target, and a single cell surface binding molecule. Applicants hereby provisionally elect, without traverse, the following species of a target cell, the genotype/phenotype of the target cell, and a cell surface binding molecule:

- 1) **Target cell: primary lymphoid cell**

Claims 1-3, 14-15, 17, 34, 35, 47, 48, 50 and 88 recite “primary lymphoid cell”; thus, they read on the elected invention. Claims 5-13, 18-23, 27-30, 33, 40-43, 45, 52, 53, 56-59, 61-64, 66-71, 83-84, 90, 93-94 and 97-99 depend from claims reciting “primary lymphoid cell,” therefore they also read on the elected invention. In addition, claims 100 and 101 read on the elected invention.

2) Genotype/Phenotype: CD3 positive

Claims 14, 47, and 100 recite “CD3 positive”; thus, they read on the elected invention. Claims 18, 22-23, 56-57 and 98 depend from claims reciting “CD3 positive,” therefore they also read on the elected invention. Finally, claims 1-3, 5-13, 15, 17, 19-21, 27-30, 33-35, 38, 40-43, 45, 48, 50, 52, 53, 58-59, 61-64, 66-71, 83, 84, 88, 90, 93-94, 97, 99, and 101 are generic claims that read on the elected invention.

3) Cell surface binding molecule: an antibody that has the same cell surface binding specificity as CD28

Claim 18 recites “an antibody that has the same cell surface binding specificity as a CD3 ligand; a CD28 ligand” and thus reads on the elected invention. Claim 98 depends from claim 18 and thus also reads on the elected invention.

Claim 21 recites “an antibody or other binding stimulatory polypeptide that has the same cell surface binding specificity as CD28” and thus reads on the elected invention.

Claim 22 recites “a CD28 binding antibody or cell surface binding fragments thereof” and thus reads on the elected invention.

Claim 23 recites “a combination of CD3 and CD28 antibodies” and thus reads on the elected invention.

Claim 52 recites “an antibody that has the same cell surface binding specificity as a CD3 ligand; a CD28 ligand” and thus reads on the elected invention.

Claim 56 recites “CD28 antibodies and cell surface binding fragments thereof” and thus reads on the elected invention.

Claim 57 recites “comprises a combination of CD3 and CD28 antibodies” and thus reads on the elected invention.

Claim 93 recites “or antibodies that have are the same cell surface binding specificity of CD3, CD25, CD28” and thus reads on the elected invention.

Claim 97 recites “comprise immobilized  $\alpha$ CD3 and  $\alpha$ CD28” and thus reads on the elected invention.

Claims 100 and 101 recite “a CD28 polypeptide” and thus read on the elected invention.

Claims 1-3, 5-15, 17, 19-20, 27-30, 33-35, 38, 40-43, 45, 47, 48, 50, 53, 58, 59, 61-64, 66-71, 83, 84, 88, 90, 94, and 99 are generic claims that read on the elected invention.

### **Reservation of Rights**

If the Patent Office withdraws the “patentably distinct species requirement,” and the elected species are held to be allowable, Applicants are entitled to consideration (examination) of additional species; and if all species are held to be allowable, a generic claim should be allowed (MPEP §809.02(c); pg 800-50, 8<sup>th</sup> Edition, rev. 2, May 2004).

Applicants expressly reserve the right under 35 U.S.C § 121 to file a divisional application directed to the non-elected subject matter during the pendency of this application, or an application claiming priority from this application.

Applicants respectfully request examination of the elected subject mater on the merits.

**CONCLUSION**

Applicants respectfully submit that all claims pending in this application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to Deposit Account No. 03-1952 referencing docket no.

**397272000401.** However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

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Respectfully submitted,

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